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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,637	04/23/2001	Robert Edward Burrell	14072-0100001	3974

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,637	BURRELL ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2005 and 10 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-8,10-16,18 and 20-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5-8,10-16,18 and 20-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/05, 6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission (IDS) filed on 6/9/2005 has been entered, as well as the IDS of 3/31/2005.

Claims 3, 5-8, 10-16, 18 and 20-26 are pending in this application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 5-8, 10-16, 18 and 20-26 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6-9, 11-29, 94-96, 99-113, and 121 of copending Application No.

10/131,511 in view of WO 98/41095. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the full reasons of record set forth below.

The above noted claims in the copending application 10/131,511 are directed to a method of reducing inflammation of an inflammatory skin condition, wherein rosacea is specifically recited as one such skin condition (e.g., claims 1, 121). The same antimicrobial metal with "sufficient atomic disorder" is utilized (see e.g., copending claims 1, 2, 4, 21). In the present application, the claims are directed to method of treating "acne conditions." Under the facts of the present application, treating "acne conditions" would encompass treating rosacea. Rosacea is also known as "acne rosacea" and it is a type of acne condition. Therefore, the ordinary skilled artisan would have recognized rosacea as an obvious condition within the scope of the claimed "acne conditions."

The copending claims do not specifically disclose the base layer and top layer claim feature of the instant application. However, use of such layers is specifically taught for atomically disordered antimicrobial metals in WO 98/41095 (page 3, lines 9-32; page 4, line 7 to page 5, line 9). The multiple layers in WO 98/41095 would operate to provide an occlusive or semi-occlusive layer which maintains the dressing in a moist condition (page 16, line 14 to page 19, line 8; see also copending claim 16).

The copending claims disclose powder sized no larger than 2 microns and particulates sized no larger than 1 micron (claims 26-27, 110-111). Further, the copending atomically disordered antimicrobial metals are nanocrystalline, and coating thickness of 150-3000 nm is disclosed (copending claim 18). Thus, utilizing nano-sized particles and particles thereof would have been fairly suggested. Additionally, the top layer in WO 98/41095 contains sufficiently atomically disordered antimicrobial metals, wherein the layer is preferably between 5-210 nm thick (page 4, lines 7-12). This suggests the atomically disordered antimicrobial metals to be in small nanometer size range, which is sufficient to meet applicant's claim feature.

Features such as atomically disordered antimicrobial metal weight percentage in a topical delivery form would have been well within the skill of the ordinary skilled artisan in this field, particularly in view of the copending claims' 0.01-10 wt% or 0.001-10 wt% range (claims 13), who would have been motivated to formulate an effective amount of a known antimicrobial substance for suitably effective antimicrobial functionality.

Therefore, the claimed invention as a whole would have been recognized as an obvious variation of the claimed invention in the copending application, 10/131,511.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 3, 5-8, 10-16, 18 and 20-26 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4-23 and 28 of copending Application No. 10/277,362 in view of WO 98/41095. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The above noted claims in the copending application 10/277,362 are directed to a method of treating a subject having a skin or integument condition, wherein one such condition is acne (see e.g., claim 5). Similar antimicrobial nanocrystalline metals with "atomic disorder" are utilized. See in said copending application, claims 1, 8-13, for example. Treating inflammatory skin conditions is disclosed (copending claim 6).

The copending claims do not specifically disclose "sufficient atomic disorder so that ... releases ... on a sustainable basis and at a concentration sufficient to provide a localized antimicrobial and anti-inflammatory effect." However, the copending claims read on all levels of atomic disorder. Further, WO 98/41095 discloses antimicrobial metals that are formed with sufficient atomic disorder such that when in contact with an alcohol or water based electrolyte, releases ions, atoms, molecules or clusters of the antimicrobial metal into the alcohol or water based electrolyte at a concentration sufficient to provide a localized antimicrobial effect on a sustainable basis (page 4, lines 13-24, page 6, lines 13-19). Hence, the ordinary skilled artisan would have been

motivated to provide such "atomic disorder" amount to the atomically disordered antimicrobial metals claimed in the copending claims.

The copending claims do not explicitly state in verbatim language, "localized anti-inflammatory effect," but such effect would have been apparent to the ordinary skilled artisan, who would have recognized similar atomically disordered antimicrobial metal, which is effective for treating acne and inflammatory skin conditions (copending claim 6).

The copending claims do not specifically disclose the base layer and top layer claim feature of the instant application. However, use of such layers is specifically taught for atomically disordered antimicrobial metals in WO 98/41095 (page 3, lines 9-32; page 4, line 7 to page 5, line 9). The multiple layers in WO 98/41095 would operate to provide an occlusive or semi-occlusive layer which maintains the dressing in a moist condition (page 16, line 14 to page 19, line 8).

The copending claims do not specifically disclose any grain sizes or particulate sizes. However, the copending atomically disordered antimicrobial metals are nanocrystalline. Thus, utilizing nano-sized particles and particles thereof would have been fairly suggested. Additionally, the top layer in WO 98/41095 contains sufficiently atomically disordered antimicrobial metals, wherein the layer is preferably between 5-210 nm thick (page 4, lines 7-12). This suggests the atomically disordered antimicrobial metals to be in nanometer size range, which is sufficient to meet applicant's claim

feature. The base layer coating, which also contains the sufficiently atomically disordered antimicrobial metal can be 300-2500 nm thick (page 4, lines 7-12).

Features such as atomically disordered antimicrobial metal weight percentage in a topical delivery form would have been well within the skill of the ordinary skilled artisan in this field, particularly in view of the copending claims' 0.01-50 wt% range (claims 22-23), who would have been motivated to formulate an effective amount of a known antimicrobial substance for suitably effective antimicrobial functionality.

Therefore, the claimed invention as a whole would have been recognized as an obvious variation of the claimed invention in the copending application, 10/277,362.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In the interest of expediting prosecution, if applicant is aware of any other copending applications in which the elected, pending and/or examined subject matter is directed to a method of treating skin conditions that may encompass or read on "acne conditions," an early filing of terminal disclaimer over such applications is suggested.

Applicant's request to hold the terminal disclaimer in abeyance as 10/131,511 has not issued as a patent is noted. However, a terminal disclaimer can be filed over a pending application -- a terminal disclaimer is not limited only to an issued patent. This

case is due on the Examiner's docket, and without the appropriate terminal disclaimer(s), the grounds of rejection cannot be withdrawn. All claims are thereby rejected.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1600